

Chairman Dingell at the Subcommittee on Oversight and Investigations hearing entitled, "Ketek Clinical Study Fraud: What Aventis Knew"

Statement of Congressman John D. Dingell, Chairman
Committee on Energy and Commerce

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS HEARING ENTITLED, "KETEK CLINICAL STUDY FRAUD: WHAT AVENTIS KNEW"
February 12, 2008

Mr. Chairman, thank you for continuing to pursue the truth regarding the Food and Drug Administration's (FDA) ill-advised approval of the antibiotic Ketek. Beyond the harm to the public health from millions of prescriptions written for this drug by doctors who relied on the FDA, this investigation raises questions about the very integrity of the drug approval process.

FDA is supposed to receive clinical trial data from manufacturers who have conducted properly designed studies that prevent serious scientific misconduct or fraud. If FDA knows or suspects such fraud and then ignores it, this Committee has every reason to probe as deeply as necessary to determine whether the entire approval process itself has been compromised.

Further, this Committee expects the full cooperation from Federal agencies when we carry out our oversight responsibility to ensure such agencies enforce the laws enacted by Congress. Given the allegations of wrongdoing in the Ketek matter, we have every right to expect FDA and the Department of Health and Human Services (HHS) to cooperate.

Instead, this Committee and other committees in Congress have repeatedly been stonewalled. Our good friend Senator Grassley, the former Chairman of the Senate Committee on Finance, who is testifying before us today, initiated inquiries into Ketek during the last Congress. He encountered the same bad faith and obstruction from this Administration.

Three of the witnesses today are FDA criminal investigators who uncovered the fraud and misconduct that will be the subject of our hearing. Unfortunately, they had to be subpoenaed to testify at this hearing because Food and Drug Commissioner von Eschenbach and Secretary Leavitt refused to allow them to appear here voluntarily. A similar refusal thwarted Senator Grassley's inquiry in the last Congress. Fortunately, with a bipartisan vote of 12-0 by this Subcommittee, we issued subpoenas for these witnesses. My friend Joe Barton, the ranking Member, and I gave the agency every opportunity to avoid this embarrassment, but to no avail.

Unfortunately, this obstructionist behavior continues. Just yesterday we received a letter from Secretary Leavitt's office, which I ask to be made part of the hearing record.

In that letter, his minions announced his refusal to honor our subpoena for records relating to Food and Drug Commissioner von Eschenbach's briefing books. I must remind my colleagues that similar records have been turned over to me, as well as my good friend Joe Barton, by both Republican and Democratic Administrations. I must also remind you that these records were also unanimously subpoenaed with a bipartisan vote of 12 to 0.

I ask my colleagues to analyze Secretary Leavitt's arguments in refusing to honor your subpoena. At best, they are

specious. At worse, they border on contempt of Congress. If anything, his refusal to cooperate causes me to wonder what he is trying to hide? What is in those briefing books that he does not want either my Republican colleagues or our side to see? Is there evidence of perjury? Are there statements embarrassing to the Administration?

Let me be clear on this point. Neither Chairman Stupak nor I will tolerate such a perversion of Congressional powers to investigate and probe. I will fully support Chairman Stupak's request to enforce this subpoena by holding Secretary Leavitt in contempt.

Mr. Chairman, there is an easy way for any agency to undergo Congressional oversight. There is also a hard way. Commissioner von Eschenbach and Secretary Leavitt appear to have chosen the latter. I caution both gentlemen to reconsider their ill-conceived notion of Congressional oversight and follow the bipartisan policies that have long been the practice of this Committee.

Prepared by the Committee on Energy and Commerce
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